U.S. FOOD & DRUG ADMINISTRATION

eCTD SUBMISSION REQUIREMENTS: WHAT YOU NEED TO KNOW

eCTD

The **Electronic Common Technical Document (eCTD)** is the standard format for submitting applications, amendments, supplements, and reports to FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER).

An eCTD submission has five modules: region-specific information, summary documents, quality-related information, nonclinical study reports, and clinical study reports.

When materials are submitted electronically, it is easier for FDA to review data, approve new drugs, and monitor drugs after they go on the market. Using eCTD also simplifies the process for submitters, because it is the same format used by drug regulatory agencies in other countries.

Starting in 2017, eCTD will be required for submissions to CDER and CBER. After the dates listed below, submissions that are not in eCTD format will not be filed or received unless exempted from the requirement.

Electronic submission requirements will apply to the following submission types:

- Commercial Investigational New Drug (IND) applications (for products that are intended to be distributed commercially)
- New Drug Applications (NDAs)
- Abbreviated New Drug Applications (ANDAs)
- Biologics License Applications (BLAs)
- All subsequent submissions to these types of applications, including amendments, supplements, and reports, even if the original submission was filed before the requirements went into effect
- Master files, such as Drug Master Files, which are considered to be submissions to an IND, NDA, ANDA, or BLA

For exemptions, please see the *Guidance for Industry, Providing Regulatory Submissions in Electronic Format - Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at www.fda.gov/ectd.

Electronic submissions must include **only** FDA fillable forms (e.g., 1571, 356h) and electronic signatures to enable automated processing of the submission. The most current FDA forms are available at www.fda.gov/AboutFDA/ReportsManualsForms/Forms. Scanned images of FDA forms will not be accepted.

Deadlines

- NDAs, ANDAs, BLAs, and master files: Starting **May 5, 2017,** must be submitted using the eCTD 3.2.2 format standard.
- INDs: Starting **May 5, 2018,** must be submitted using the eCTD standard.

Updates to the standard will be announced on the FDA website and published in the *Federal Register*.

Additional Information

Visit www.fda.gov/ectd to find all of the relevant guidances and technical specifications for eCTD and a step-by-step guide to setting up an Electronic Submissions Gateway account.

For additional questions, please contact esub@fda.hhs.gov (CDER) or esubprep@fda.hhs.gov (CBER)

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES/U.S. FOOD & DRUG ADMINISTRATION
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